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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,159	12/01/2003	Erming Xia	P03366	4792
23702	7590	01/03/2006	EXAMINER	
Bausch & Lomb Incorporated One Bausch & Lomb Place Rochester, NY 14604-2701			VANIK, DAVID L	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,159	XIA ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6,7,9-12 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,6,7,9-12 and 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the Applicant's Remarks and Amended Claims filed on 9/29/2005.

The 35 USC §102 rejections over US Patent 6,274,133 ('133) are hereby **maintained**. As a result of Applicant's Amendment, the 35 USC §102 rejections over 4,436,730 ('730) and US patent 6,274,133 ('133) are hereby **withdrawn**. It should be noted that both '730 and '133 appear to require the presence of antimicrobial agents.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-4, 6-7, 9-12, 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 6,274,133 ('133).

'133 disclose a method for treating a contact lens with a solution (abstract). The method comprises contacting the surface of a contact lens with a solution comprising a cationic cellulose polymer, a tonicity agent, and a buffering agent (claim 1). Cellulose polymers are a well-known example of polysaccharides. According to '133, a wetting agent can be added to the contact lens solution (Claims 4-5). The wetting agent can comprise mono or disaccharides (claim 5). Thus, the contact lens solution advanced by '133 comprises a cationic polysaccharide and a saccharide. It should be noted that the examiner is interpreting a contact lens as a type of medical device.

It is the examiner's position that, inherently, the contact lens solution advanced by '133 would eliminate a "microbial burden" when soaked with the contact lens. Since the essential elements of the '133 composition are identical to the instant composition (that is, a contact solution comprising a cationic polysaccharide and a saccharide), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '133 anticipates the compositions enumerated in the instant claim set.

The claims are therefore anticipated by US patent 6,274,133 ('133).

Arguments

Applicant's arguments filed on 9/29/2005 have been fully considered but they are not persuasive. In response to the 7/18/2005 Non-Final Rejection, Applicant has

changed the claim language in the independent claims 20-21 from the open phraseology "comprising," to the partially closes phraseology "consisting essentially of." As a result of this amendment, Applicant asserts that '133 does not anticipate the instant claim set because '133 requires a "disinfecting amount of a preservative antimicrobial agent." The examiner respectfully disagrees with this assertion.

As set forth above, '133 disclose a method for treating a contact lens with a solution (abstract). The method comprises contacting the surface of a contact lens with a solution comprising a cationic cellulose polymer, a tonicity agent, and a buffering agent (claim 1). Cellulose polymers are a well-known example of polysaccharides. According to '133, a wetting agent can be added to the contact lens solution (Claims 4-5). The wetting agent can comprise mono or disaccharides (claim 5). Thus, the contact lens solution advanced by '133 comprises a cationic polysaccharide and a saccharide.

As set forth in claims 1-13 of '133, there is no requirement of a preservative or antimicrobial agent. As such, the contact solution advanced by '133 can include (1) a cationic cellulose polymer, (2) a tonicity agent, (3) a buffering agent, and a (4) mono or disaccharide (Claims 1-5). It is the examiner's position that the addition of a tonicity agent and buffering agent does not materially alter the function of the cationic cellulose polymer/saccharide-based solution. As a result, it is the examiner's position that the instant claims are anticipated by US patent 6,274,133 ('133).

NEW REJECTIONS:

The following is a list of new rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Independent claims 20 and 21 are rejected and dependent claims 3-4, 6-7, 9-12, 16-19 are objected to under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cationic polysaccharides, does not reasonably provide enablement for the generic class of polysaccharides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: breadth of the claims; nature of the invention; state of the prior art; amount of direction provided by the inventor; the level of predictability in the art; the existence of working examples; quantity of experimentation needed to make or use the invention based on the content of the disclosure; and relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

The breadth of claims: Claims 20-21 are drawn to a composition comprising polysaccharides together with saccharides. The "polysaccharides" limitation added by claims 20-21 is very broad, one that is not supported by the instant specification.

The nature of the invention: The invention is drawn to a composition comprising cationic polysaccharides together with saccharides. The rejected claims 20-21 are drawn to a composition comprising polysaccharides together with saccharides.

The amount of direction provided by the inventor: There is nothing in the specification that would indicate that a composition comprising any type of polysaccharide together with saccharides could effectively operate as a gentle preservative system. Polysaccharides comprise a very broad class of chemical species and can include cationic, non-ionic, and anionic polysaccharides. Guidance for preparing and using a composition comprising all the possible combinations of "polysaccharides" is not provided in the instant specification. With respect to the instant composition, there is a substantial gap between a composition comprising cationic polysaccharides and the entire gamut of "polysaccharides." Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

The presence or absence of working examples: Thirteen examples are included in the instant specification. The scope of all of these examples revolve around the use of cationic polysaccharides. Applicant fails to provide examples of compositions comprising any other polysaccharides outside of the scope of cationic polysaccharides. As such, the practitioner would turn to trial and error experimentation in order to compose a gentle preservative composition comprising any polysaccharide together with a saccharide, without guidance from the specification or the prior art.

The quantity of experimentation: In the instant case, there is a substantial gap between a composition comprising cationic polysaccharides, and one comprising any and all "polysaccharides" As stated earlier, "polysaccharides" comprise a huge class of compounds. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap

The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

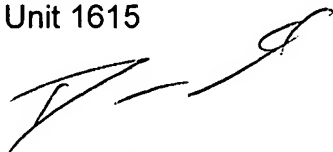
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615



12/23/05



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